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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,386	12/05/2005	Hiromitsu Nakauchi	790086.406USPC	2881

500 7590 01/03/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
01/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,386	NAKAUCHI ET AL.	
	Examiner	Art Unit	
	Laura M. Mitchell	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, drawn to a composition comprising active STAT5 wherein the active STAT5 is a **polypeptide**, and comprising a cellular physiologically active substance and an agent capable of activating STAT5.

Group II, claim(s) 22-37, drawn to a composition comprising a **nucleic acid molecule** encoding active STAT5 polypeptide and comprising a cellular physiologically active substance.

Group III, claim(s) 38-47, drawn to a method for maintaining the expansion, pluripotency or self-replication ability of a stem cell by providing STAT5 to the cell, or an agent capable of activating the STAT5 to the cell and a cell, a tissue and an organ.

Group IV, claim(s) 48-51, drawn to a medicament composition, a method for treating or preventing a disease or disorder comprising administration of a cell obtained by treating with active STAT5 and a method for producing a medicament for treatment or prophylaxis of a disease or disorder.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claims lack unity of invention and lack a special technical feature that defines a contribution over the prior art because Applicants' claimed composition comprising active STAT5 was known in the prior art (See McKnight et al U.S. Patent No. 5,618,693, 4/8/1997). McKnight et al teaches a composition comprising the translation product of the cDNA for human STAT5 (see column 2, lines 40-60). Absent contrary evidence this STAT5 would be active. A STIC search of the sequence of SEQ ID NO:2 revealed that it is 100% identical to SEQ ID NO:2 taught by McKnight et al.

The technical feature of Group I is a composition comprising active STAT5 that is a polypeptide as set forth in SEQ ID NO:2, while the technical feature of Group II which distinguishes it from Group I is a nucleic acid that encodes STAT5. The technical

feature of Group III is a method for maintaining stem cells comprising providing active STAT5 to the cells. The technical feature of Group IV is a method for treatment of a disease comprising the step of administering a cell that has been obtained by treating a stem cell with active STAT5.

Groups I-II are each drawn to products. The methods of Groups III-IV involve distinct methods of use of the compositions comprising the STAT5 polypeptide, therefore the product composition of Group I can be used for either method. The methods of Groups III-IV involve distinct methods of use of the composition comprising a nucleic acid sequence encoding STAT5, therefore the product composition of Group II can be used for either method.

The method of Group III is distinguished from the method of Group IV by the step of providing active STAT5 to a stem cell, which is not found in the method of Group IV. The method of Group IV is distinguished from the method of Group III by the step of administering a cell that has been produced by treating a stem cell with active STAT5 to a patient with a disease or disorder, which is not found in the method of Group III.

The outcomes of the methods of Groups III-IV can be distinguished from one another. The outcome of the method of Group III is a cell with expanded pluripotency, which is distinct from the outcomes of the method of Group IV. The outcome of the method of Group IV is a patient treated with a cell treated with active STAT5, which is distinct from the outcomes of the method of Group III.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. (a) Polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO:2 (human amino acid sequence of STAT5A)** or a fragment thereof; (b) a polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 2 having at least one mutation selected from at least one amino acid substitution, addition and deletion, and having biological activity; (c) a polypeptide encoded by an allelic variant of a base sequence set forth in **SEQ ID NO:1 (human nucleic acid sequence of STAT5A)**; (d) a polypeptide which is a species homolog of an amino acid sequence set forth in SEQ ID NO:2;or (e) a polypeptide having an amino acid sequence having at least 70% identity to any one of the polypeptides (a) to (d), and having biological activity; and wherein in the active STAT5, at least one serine, threonine, or tyrosine residue is phosphorylated.

2. (a) Polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO: 4 (human amino acid sequence of STAT5B)** or a fragment thereof; (b) a polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 4 having at least one mutation selected from at least one amino acid substitution, addition and deletion, and having biological activity; (c) a polypeptide encoded by an allelic variant of a base sequence set forth in **SEQ ID NO:3 (human nucleic acid sequence of STAT5B)**; (d) a polypeptide which is a species homolog of an amino acid sequence set forth in SEQ ID NO:4;or (e) a polypeptide having an amino acid sequence having at least 70% identity to any one of the polypeptides (a) to (d), and having biological activity; and wherein in the active STAT5, at least one serine, threonine, or tyrosine residue is phosphorylated.

3. (a) Polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO:6 (mouse amino acid sequence of STAT5A)** or a fragment thereof; (b) a polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 6 having at least one mutation selected from at least one amino acid substitution, addition and deletion, and having biological activity; (c) a polypeptide encoded by an allelic variant of a base sequence set forth in **SEQ ID NO:5 (mouse nucleic acid sequence of STAT5A)**; (d) a polypeptide which is a species homolog of an amino acid sequence set forth in SEQ ID NO:6;or (e) a polypeptide having an amino acid sequence having at least 70% identity to any one of the polypeptides (a) to (d), and having biological activity; and wherein in the active STAT5, at least one serine, threonine, or tyrosine residue is phosphorylated.

4. (a) Polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO:8 (mouse amino acid sequence of STAT5B)** or a fragment thereof; (b) a polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 6 having at least one mutation selected from at least one amino acid substitution, addition and deletion, and having biological activity; (c) a polypeptide encoded by an allelic variant of a base sequence set forth in **SEQ ID NO:7 (mouse nucleic acid sequence of STAT5B)**; (d) a polypeptide which is a species homolog of an amino acid sequence set forth in SEQ ID

NO:8;or (e) a polypeptide having an amino acid sequence having at least 70% identity to any one of the polypeptides (a) to (d), and having biological activity; and wherein in the active STAT5, at least one serine, threonine, or tyrosine residue is phosphorylated.

5. SEQ ID NO:10 **(amino acid sequence of STAT5A 1*6, a variant of STAT5A).**
6. SEQ ID NO:13 **(amino acid sequence of STAT5A 1*7, a variant of STAT5A).**

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 2-3, 5-6, 8, 14-18 and 20-21 correspond to species 1-6.
Claim 4 corresponds to species 1 and 3.
Claim 7 corresponds to species 1.
Claim 9-12 corresponds to species 1 and 3.
Claim 13 corresponds to species 5 and 6.

The following claim(s) are generic: claims 1 and 19.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species lack the same or corresponding technical feature because Applicants' claimed sequence comprising STAT5 was known in the prior art (See McKnight et al U.S. Patent No. 5,618,693, 4/8/1997). McKnight et al teach a composition comprising the translation product of the cDNA for human STAT5 (see column 2, lines 40-60). A STIC search of the sequence of SEQ ID NO:2 revealed that it is 100% identical to SEQ ID NO:2 taught by McKnight et al.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. (a) Polynucleotide having a base sequence set forth in **SEQ ID NO:1 (human nucleic acid sequence of STAT5A)** or a sequence fragment thereof; (b) a polynucleotide encoding a polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO:2 (human amino acid sequence of STAT5A)**, or a fragment thereof; (c) a polynucleotide encoding a variant polypeptide having an amino acid sequence set forth in SEQ ID NO:2 having at least one mutation selected from the group consisting of at least one amino acid substitution, addition and deletion, and having biological activity; (d) a polynucleotide which is an allelic variant of DNA consisting of a base sequence set forth in SEQ ID NO:2; (e) a polynucleotide encoding a species homolog of a polypeptide consisting of an amino acid sequence set forth in SEQ ID NO:2 (f) a polynucleotide encoding a polypeptide hybridizable to any one of the polynucleotides (a) to (e) under stringent conditions, and having biological activity; or (g) a polynucleotide consisting of a base sequence having at least 70%identity to any one of the polynucleotides (a) to (e) or a complementary sequence thereof, and having biological activity.

2. (a) Polynucleotide having a base sequence set forth in **SEQ ID NO:3 (human nucleic acid sequence of STAT5B)** or a sequence fragment thereof; (b) a polynucleotide encoding a polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO:4 (human amino acid sequence of STAT5B)**, or a fragment thereof; (c) a polynucleotide encoding a variant polypeptide having an amino acid sequence set forth in SEQ ID NO:4 having at least one mutation selected from the group consisting of at least one amino acid substitution, addition and deletion, and having biological activity; (d) a polynucleotide which is an allelic variant of DNA consisting of a base sequence set forth in SEQ ID NO4; (e) a polynucleotide encoding a species homolog of a polypeptide consisting of an amino acid sequence set forth in SEQ ID NO:4; (f) a polynucleotide encoding a polypeptide hybridizable to any one of the polynucleotides (a) to (e) under stringent conditions, and having biological activity; or (g) a polynucleotide consisting of a base sequence having at least 70% identity to any one of the polynucleotides (a) to (e) or a complementary sequence thereof, and having biological activity.

3. (a) Polynucleotide having a base sequence set forth in **SEQ ID NO:5 (mouse nucleic acid sequence of STATA)** or a sequence fragment thereof; (b) a polynucleotide encoding a polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO:6 (mouse amino acid sequence of STAT5A)**, or a fragment thereof; (c) a polynucleotide encoding a variant polypeptide having an amino acid sequence set forth in SEQ ID NO:6 having at least one mutation selected from the group consisting of at least one amino acid substitution, addition and deletion, and having biological activity; (d) a polynucleotide which is an allelic variant of DNA consisting of a base sequence set forth in SEQ ID NO:6; (e) a polynucleotide encoding a species homolog of a polypeptide consisting of an amino acid sequence set forth in SEQ ID NO:6; (f) a polynucleotide encoding a polypeptide hybridizable to any one of the polynucleotides (a) to (e) under stringent conditions, and having biological activity; or (g) a polynucleotide consisting of a base sequence having at least 70% identity to any one of the polynucleotides (a) to (e) or a complementary sequence thereof, and having biological activity.

4. (a) Polynucleotide having a base sequence set forth in **SEQ ID NO:7 (mouse nucleic acid sequence of STATB)** or a sequence fragment thereof; (b) a polynucleotide encoding a polypeptide consisting of an amino acid sequence set forth in **SEQ ID NO:8 (mouse amino acid sequence of STAT5B)**, or a fragment thereof; (c) a polynucleotide encoding a variant polypeptide having an amino acid sequence set forth in SEQ ID NO: 8 having at least one mutation selected from the group consisting of at least one amino acid substitution, addition and deletion, and having biological activity; (d) a polynucleotide which is an allelic variant of DNA consisting of a base sequence set forth in SEQ ID NO: 8; (e) a polynucleotide encoding a species homolog of a polypeptide consisting of an amino acid sequence set forth in SEQ ID NO: 8; (f) a polynucleotide encoding a polypeptide hybridizable to any one of the polynucleotides (a) to (e) under stringent conditions, and having biological activity; or (g) a polynucleotide consisting of a base sequence having at least 70% identity to any one of the polynucleotides (a) to (e) or a complementary sequence thereof, and having biological activity.

5. SEQ ID NO:10 **(amino acid sequence of STAT5A 1*6, a variant of STAT5A).**
6. SEQ ID NO:13 **(amino acid sequence of STAT5A 1*7, a variant of STAT5A).**
7. SEQ ID NO:9 **(nucleic acid sequence of STAT5A 1*6, a variant of STAT5A).**

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 23-24, 29-31 and 34-37 correspond to species 1-6.
Claim 25-28 corresponds to species 1 and 3.
Claim 32 corresponds to species 7.

The following claim(s) are generic: claims 22 and 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species lack the same or corresponding technical feature because Applicants' claimed sequence comprising STAT5 was known in the prior art (See McKnight et al(U.S. Patent No. 5,618,693, 4/8/1997). McKnight et al teaches a composition comprising the translation product of the cDNA for human STAT5 (see column 2, lines 40-60). McKnight et al teach a nucleic acid sequence of STAT5 (SEQ ID NO:1) and a STIC search of the sequence of SEQ ID NO:2 revealed that it is 100% identical to SEQ ID NO:2 taught by McKnight et al. Absent evidence to the contrary SEQ ID NO:1 taught by McKnight et al would be identical to instant SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura M. Mitchell whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura M. Mitchell
Examiner
12/20/2007

CELINE QIAN, PH.D.
PRIMARY EXAMINER